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CLIENT MATTER NO.:

QUIG-1006USCIP

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JUN 2 4 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Richard A. Rosenbloom

Group Art Unit:

Application No.:

10/045,790

1617

Examiner:

Filing Date:

S.A. Jiang, Ph.D.

January 14, 2002

Attorney Docket No.:

Oral Compositions And Methods

QUIG-1006USCIP

For Prevention, Reduction And

Treatment of Radiation Therapy

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(e)(1)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and 1.97(e), Applicants bring to the attention of the Examiner the documents listed on the attached Substitute Form PTO 1449 (in duplicate). No fee is believed to be due in connection with this submission. However, is any fee is due; the Commissioner is authorized to charge Deposit Account No. 50-0462. Moreover, please credit any overpayment to Deposit Account No. 50-0462.

CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R.§1.8

I certify that this document, along with any document referred to as being attached, is being facsimiled on June 24, 2004, under 37 C.F.R. §1.8 to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22373-1450.

Name of person signing document

Certification Under 37 CFR 1.97(e)(1)

The references cited in this Information Disclosure Statement were cited in the International Search Report dated May 25, 2004 from the International Searching Authority in the corresponding international application (PCT/US03/33415). This Information Disclosure Statement is being filed within three months from the International Search Report.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached Substitute PTO 1449 form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If the Examiner applies the documents as prior art against any claims in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the Patent Office the relevant facts and law regarding the appropriate status of such documents. Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Respectfully submitted,

Kevin J. Dunleavy

Registration No. 32

Customer No. 21302 KNOBLE YOSHIDA & DUNLEAVY

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Page 1 (U.S. Patents)

FORM PTO-1449 Modified Documents Cited by Applicant U.S. App. No.: 10/045,790 Filed: January 14, 2002 Group: 1617

Applicant:Rosenbloom

Examiner	Item	;			cket No.:QUIG-1006	;
Initial	No.	Document No.	Date	Name	Class	Subclass
<u> </u>	1US	5,776,460	July 7, 1998	Kim et al.	!	!
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	3US	!				<u> </u>
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

O3	FOR FURTHER ACTION	(Form PC	T/ISA/220) as well as, where applicable, item 5					
	International filing date (day/month/year) 22 October 2003 (22.10.2003)		(Earliest) Priority Date (day/month/year) 24 October 2002 (24.10,2002)					
Applicant THE QUIGLEY CORPORATION								
This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau. This international search report consists of a total of sheets. It is also accompanied by a copy of each prior art document cited in this report. 1. Basis of the Report a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item. the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)). b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:								
filed together with the inter- furnished subsequently to the furnished subsequently to the the statement that the subsec- international application as: the statement that the information furnished. Certain claims were found Unity of invention is lacking egard to the title,	national application in computer rais Authority in written form. is Authority in computer readable quently furnished written sequence filed has been furnished. nation recorded in computer reada unsearchable (See Box I). Ig (See Box II).	form. e listing doe ble form is	s not go beyond the disclosure in the					
the text is approved as submithe text has been established may, within one month from Authority. The of the drawings to be published as suggested by the applicant failed to	according to Rule 38.2(b), by the date of mailing of this internst lished with the abstract is Figure to suggest a figure.	itional searc						
	al application No. //33415 GLEY CORPORATION Cational search report has bee according to Article 18. A cational search report consists It is also accompanied the Report With regard to the language, language in which it was filled the international search was Authority (Rule 23.1(b)). With regard to any nucleotide search was carried out on the contained in the international filed together with the international subsequently to the statement that the subsequently to the statement that the informational application as the statement that the information is lacking the text is approved as submitthe text has been established egard to the abstract, the text is approved as submitthe text has been established may, within one month from Authority. The contained the applicant failed the cause th	ACTION al application No. //33415 International filing date (day/ma 22 October 2003 (22.10.2003) ACTION International filing date (day/ma 22 October 2003 (22.10.2003) Actional search report bas been prepared by this International according to Article 18. A copy is being transmitted to the International search report consists of a total of sheets. It is also accompanied by a copy of each prior art document of the Report With regard to the language, the international search was carriellanguage in which it was filed, unless otherwise indicated under the international search was carried out on the basis of a transmutority (Rule 23.1(b)). With regard to any nucleotide and/or amino acid sequence dissearch was carried out on the basis of the sequence listing: contained in the international application in written form. filed together with the international application in computer readable the statement that the subsequently furnished written sequence international application as filed has been furnished. Certain claims were found unsearchable (See Box I). Unity of invention is lacking (See Box II). The text is approved as submitted by the applicant. the text has been established by this Authority to read as followed to the abstract, the text has been established, according to Rule 38.2(b), by the may, within one month from the date of mailing of this internal Authority.	ACTION [Food Policy of Eclow Policy of Pol					

International application No.

PCI/USU	PC17US(B/33415							
A. CLASSIFICATION OF SUBJECT MATTER IPC(7): A61K 7/42, 7/44, 31/59, 31/58, 31/20 US CL: 4724/59, 60; 514/167, 170, 558 According to International Patent Classification (IPC) or to both pational classification and IPC								
B. FIELDS SEARCHED								
Minimum documentation searched (classification system followed by classification symbols) U.S.: 4724/59, 60; 514/167, 170, 558								
Documentation searched other than minimum documentation to the extent that such documents are	included in the fields searched							
Electronic data base consulted during the international search (name of data base and, where pract	inable manufactured							
UAPATFULL, PCTFULL, WPIDS	seator scarca in 1860)							
C. DOCUMENTS CONSIDERED TO BE RELEVANT								
Category * Citation of document, with indication, where appropriate, of the relevant passage								
Y WO 97/18817 A1 (KITA, KTYOSHI) 29 May 1997 (29.05.1997), abstact and entire patent.								
Y US 5,571,441 A (ANDON et al.) 5 November 1996 (05.11.1996), abstract, column and 10-14, and claims 1-20.								
Y US 5,776,460 A (KIM et al.) 7 July 1998 (07.07.1998), column 1 lines 21-27.	1-25							
	-							
•	<u> </u>							

See patent family amex.

when the document is taken alone

being obvious to a person skilled in the art

document member of the sums patent family

25 MAY 2004

Date of mailing of the international search report

Sreeni Padmanabhan 7.

Telephone No. (571) 272-1600

later document published after the interestional filing date or priority

date and not in conflict with the application but ched to understand the principle or theory underlying the invention

document of particular relevance; the claimed invention cannot be considered nevel or cannot be considered to involve at inventive step

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination

INTERNATIONAL SEARCH REPORT

Form PCT/ISA/210 (second sheet) (July 1998)

Name and mailing address of the ISA/US

Mati Stop PCT, Aun: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Further documents are listed in the continuation of Box C.

document defining the general state of the art which is not considered to be

"E" exclier application or putent published on or after the international filing date

document which may throw doubte on priority claim(s) or which is exted to establish the publication date of another citation or other special reason (as

document referring to an oral displacare, use, exhibition or other means

document published prior to the international filling data but later than the

Date of the actual completion of the international search

Special categories of cited documents:

"A"

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of particular relevance

priority due claimed

09 Jamary 2004 (09.01.2004)

Facsimile No. (703)305-3230

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (n) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
 "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers;
 claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- 2. [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
- [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
 "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- [Where various kinds of amendments are made]:
 "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claims 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Burean, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first translation of such amendments, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed

For further details on the requirements of each designated/elected Office, see the PCT Applicant's Guide, Volume II.